K002343

JUN - 8 2001

Your Ref:

Our Ref:

Penlon

Inter Med

Penlon Limited
Radley Road
Abingdon
Oxon OX14 3PH

Telephone: +44 (0)1235 547000
Customer Service: +44 (0)1235 547001
Fax: +44 (0)1235 547041
Sales Fax: +44 (0)1235 547021
Service Fax: +44 (0)1235 547031

12 510(k) Summary

Submitter

Anthony Parsons
Penlon Ltd
Radley Road
Abingdon
Oxon OX12 7LL

Tel (+) 1235 547000
Fax (+) 1235 547032
email aparsons@penlon.co.uk

Proprietary Name	Sigma Delta anaesthesia vaporizer
Common name	Anaesthetic vaporizer
Classification Name	Anaesthetic vaporizer 21 CFR 868.5160

Devices to which substantial equivalence is claimed:

Penlon	Sigma Elite Vaporizer	(k) 936046
Penlon	Sigma Elite (Sevoflurane variant)	(k) 942545
Penlon	Quik-Fil Vaporizer Keyed Filler	(k) 961468
North American Draeger	Vapor 2000	(k) 971923
Ohmeda	Tec 5	(k) 892057
Siemens	Sevoflurane Vaporizer	(k) 980884

Qualification of the Sigma Delta vaporizer include hazard analysis, functional, communication, environmental and electromagnetic compatibility testing.

Device Description

The Sigma Delta is an anaesthestic vaporizer.

Intended use

The Delta range of vaporizers are concentration calibrated vaporizers designed to deliver accurate concentrations of volatile anaesthetic agent into the fresh gas supply of a continuous flow anaesthetic machine when connected directly between the flowmeter and the common gas outlet of the anaesthesia machine. The Delta range will replace the Sigma range of vaporizers in the USA.

Substantial Equivalence

The Sigma Delta and all of the above vaporizers are designed for vaporizing liquid anaesthetic agents in conjunction with the controlled administration of anaesthetic gas mixtures during surgery. The Sigma Delta is intended to be used by Healthcare providers, i.e. Physicians, Nurses and Technicians during anaesthesia on Adult, Paediatric, Infant and Neonatal populations.

The Sigma Delta is substantially equivalent in operation to all of the above by-pass type vaporizers in which the carrier gas passes through the vaporizer via two channels, one leading through a by-pass route and the other through the vaporization **chamber**. The proportion of gas passing through the vaporization chamber is partially controlled by a calibrated **control dial**, and partially by a **temperature responsive device** outside the vaporization chamber. In the chamber, a series of **wicks** are saturated with agent, presenting a very large area from which the agent evaporates, and such an arrangement ensures that the gases passing through the vaporization chamber are saturated with vapour.

The percentage of agent vapour at the outlet of the vaporizer depends on the amount of vapour laden gas exiting the vaporization chamber that is mixed with the fresh carrier gas passing through the by-pass route. As the temperature within the vaporization chamber falls (and, therefore, as the vapour concentration in the gas passing through it also falls), the temperature compensator closes or restricts the by-pass route and a greater proportion of the total gas flow passes through the chamber. Thus, the use of a temperature responsive device allows the vapour concentration at the outlet of the vaporizer to remain constant.

The Delta has direct equivalency to individual features of the predicate devices as follows:-

Plenum Chamber

The Delta plenum chamber is constructed from anodised aluminium and is directly equivalent to that used on the Siemens vaporizer. Both chambers are designed to contain anaesthetic agent in the liquid form.

Control Dial

The control of all the predicate devices is by means of a dial situated on either the front or the top of the vaporizers. The push and turn dial of the Delta vaporizers is directly equivalent to that of the Sigma Elite. The control needle that is operated from the dial is also the same design as that used on the Sigma Elite. As can be seen from the feature table above the use of a guided needle is a common means of controlling the flow from the plenum chamber. The dial also operates the interlock backbar system. The Delta interlock system is directly equivalent to the Sigma Elite.

Temperature Responsive Device

The Delta vaporizer incorporates a temperature responsive device which utilises a bi-metallic strip that deflects according to its temperature to control the resistance offered to the flow of gas through it. An identical device is used on the Tec 5 vaporizer. Both temperature devices are located as close as possible to the liquid agent to achieve a rapid response to changes in liquid agent temperature.

Wick

The copper coiled wick used on the Delta vaporizer is identical to that used on the Sigma Elite. The wicking material has been changed from sintered PTFE to PTFE needle felt. A coiled PTFE needle felt wick is also used on the Drager vaporizer.

Filler Systems

The Delta vaporizer can be specified with either Pour fill, Pin index or Quik Fil filling systems. The Pour fill and Pin index systems are made available by all the listed vaporizer manufacturers and are compliant to international standards. The Quik Fil system is identical in operation to the predicate Penlon Quik-Fil Vaporizer Agent Specific Filler.

Back Bar Fitting

The Delta vaporizer can be specified with either Selectatec, Cagemount, Drager 'Plug-in', or North American Drager Compatible (interlock) backbar. The first three aforementioned backbars have been included with previous Sigma Elite submissions. The Penlon NAD Drager (interlock) backbar is equivalent to that which can be specified on the Drager vaporizer.

As can be seen from the above descriptions the Sigma Delta is substantially equivalent in design concepts, technologies and materials to several predicate devices. In particular the Sigma Delta incorporates many design features that were originally incorporated in the Sigma Elite.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2001

Mr. Anthony Parsons
Penlon Ltd.
Radley Road
Abingdon, OX14 3PH
ENGLAND

Re: K002343
Anaesthetic Vaporizer
Regulation Number: 868.5880
Regulatory Class: II (two)
Product Code: 73 CAD
Dated: March 16, 2001
Received: March 21, 2001

Dear Mr. Parsons:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8.0 Labelling - Statement of indications for use

510(k) Number (if known): K002343

Device Name: Anaesthetic vaporizer

Indications for use:

The Sigma Delta Vaporizers vaporizes a specific anaesthetic agent either halothane, isoflurane, enflurane or sevoflurane and delivers controlled concentrations of the vaporized anaesthetic agent into a fresh gas that is then breathed by the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence ofCDRH, Office of Device Evaluation

Division of Cardiovascular & Respiratory Devices
510(k) Number K002343

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____